THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

May 11, 2010

The Honorable Charles E. Grassley
United States Senate
Washington DC 20510

Dear Senator Grassley:

Thank you for your letter regarding the status of the 2009 H1N1 vaccine procured by the Department of Health and Human Services (HHS) and our plans to protect the country from the threat of H1N1 influenza in the future. I greatly appreciate your continued interest in and support for this important effort. Answers to the specific questions you raised in your letter are provided below.

1) How many doses of vaccine are due to expire on June 30, 2010?

The Department of Health and Human Services (HHS) ordered a total of 229 million bulk doses of monovalent 2009 H1N1 vaccine from the five vaccine manufacturers. Of these, the manufacturers filled and finished 199 million doses. After taking into account doses not delivered or returned for product recalls, doses provided to the Department of Defense, and international commitments, 162.5 million doses were made available for use by the U.S. public. Based on the current levels of vaccine use, by June 30, 2010 approximately 40 million doses of the 2009 H1N1 vaccine made available for the public will have expired before being used.

2) What are the other expiration dates for the remaining inventory and what are the Department's plans for dispensing of these vaccines to limit the number of doses that will be discarded?

We do not know with certainty the mix of expired and unexpired vaccines currently held by states. There are, however, approximately 14.3 million doses of vaccine usable beyond June 30, 2010 that either remain at the CDC distribution center or are being stored by the manufacturer. Of these, approximately 7.6 million doses are currently at the CDC distribution center; these doses will expire during May and June of 2011. When the current distribution contract with McKesson Specialty ends, these doses will be transferred to a federal facility where they will be stored until they are requested by the states, or they expiration.

Over the last several months, the states' demand for vaccine has steadily decreased. Due to the time needed for transportation and storage, vaccine doses with an expiration date on or before May 30, 2010 are no longer being distributed; therefore, any orders are being filled with doses that expire in 2011. HHS is encouraging states to retain vaccine until further notice (or through expiration) in case disease increases before the 2010-2011 seasonal vaccine, which will include the 2009 H1N1 strain, becomes available. Additionally, we anticipate that demand for vaccine may increase in the lead-up to the 2010-2011 flu season (and before the seasonal vaccine is available), at which point the remaining doses would be available to the states for distribution.

3) As of the date of this letter, how many doses of 2009 H1N1 vaccines were filled and finished in vials, syringes, and sprayers? Are there plans to fill and finish any more of the bulk vaccine?

The breakdown of the total number (199 million) of filled and finished 2009 H1N1 vaccine doses follows:

- 34.5 million doses in pre-filled syringes;
- 32.0 million doses in intranasal sprayers; and
- 132.5 million doses in multidose vials.

HHS continues to monitor the demand for 2009 H1N1 monovalent vaccine but has not recently ordered more vaccine to be filled and finished. If demand increases and the current supplies are at risk of being insufficient, HHS will order the filling and finishing of additional vaccine to ensure a steady and adequate supply.

4) It is my understanding that there is one distribution depot for the entire nation, Memphis, TN. What are the contingency plans should this depot become unserviceable?

As the pandemic lessened in intensity, to conserve resources, CDC worked with McKesson Specialty to consolidate the vaccine supply from the four original depots into one distribution center to conserve resources. If the current distribution depot became unserviceable, McKesson would provide CDC with an alternative plan/depot.

5) According to the Flu.gov website, protection against the H1N1 flu virus will be included in the seasonal flu vaccine for the 2010-2011 flu season. What effect will this have on the current 2009 H1N1 vaccine inventory?

As we plan for the 2010-2011 seasonal influenza vaccine campaign, HHS will encourage the public to obtain the seasonal vaccine, which will contain protection against 2009 H1N1 as part of its formulation. We anticipate that in the lead-up to the availability of the seasonal vaccine, there may be some increase in demand for the monovalent 2009 H1N1 vaccine. Therefore, we are encouraging States to maintain a supply of the 2009 H1N1 monovalent vaccine to meet this demand. This supply will also serve as a safeguard in case of any manufacturing delays in the seasonal vaccine. The current inventory of the monovalent 2009 H1N1 vaccine is such that we anticipate that it will be sufficient to meet any increase in demand.

6) The 2009 H1N1 vaccines were purchased entirely by HHS and distributed to the states. Given that the seasonal flu vaccine will include protection against the H1N1 flu strain for the 2010-2011 flu season, does the Department plan to increase its purchase of the number of seasonal flu vaccines for the 2010-2011 flu season? If so, does that mean HHS will also be extending the Public Readiness and Emergency Preparedness Act declaration for pandemic vaccines to include the seasonal flu vaccine?

At this time, HHS plans to increase its direct purchase of the 2010-2011 seasonal influenza vaccine through mechanisms including the Vaccines for Children Program, Section 317 Program,

and the Recovery Act. However, as in other flu seasons, the majority of seasonal influenza vaccines will be purchased by the private sector.

The PREP Act declaration for pandemic influenza vaccines was recently extended through February 28, 2012. However, that declaration does not cover vaccines against virus strains included in seasonal influenza vaccines and/or covered under the National Vaccine Injury Compensation Program. The National Vaccine Injury Compensation Program will continue to provide compensation to any people found to be injured by the seasonal flu vaccine. More information regarding this program can be found here: http://www.hrsa.gov/vaccinecompensation/.

7) According to your response, over 70 percent of the Department's orders of 2009 H1N1 vaccine had been completed, with about $1.2 billion invoiced as of the date of your response. According to press reports in September 2009, the Obama Administration earmarked $1.8 billion in July for H1N1 flu and another $2.7 billion in September for new vaccines, antiviral drugs and a vaccination campaign. To date, how much of the appropriated dollars from Congress has been obligated and expended? Please provide a breakdown of the spending by HHS and its agencies.

Please see the attached table for a breakdown of the fiscal year (FY) 2009 supplemental pandemic influenza funding allotted, obligated, and expended by HHS agencies. Original plans for the vaccine funding assumed that two doses of 2009 H1N1 vaccine would be needed in order to provide protection against the virus. Since the 2009 H1N1 vaccine is well-matched to the virus and highly immunogenic, less FY 2009 supplemental funding was needed to purchase doses for Americans than originally projected, so the obligations and expenditures are significantly lower than the amount allocated. HHS plans to use balances from the FY 2009 supplemental for future preparedness activities.

Thank you again for your letter and for your continued commitment to our nation's public health preparedness. I look forward to further collaboration with you on these important issues.

Sincerely,

Kathleen Sebelius

Enclosure

Department of Health and Human Services
Pandemic Influenza
FY 2009 Supplemental Obligations and Outlays as of February 28, 2010
($ in millions)

Activities Funded with FY 2009 Emergency Funding:	Allocations	Obligations	Outlays
Vaccine Production (ASPR)	3,048.3	1,637.0	1,408.0
Antivirals (ASPR)	231.5	231.3	22.3
Deployment/Operations Support (ASPR)	56.0	0.4	0.2
Vaccine Development (FDA)	10.0	6.9	0.4
Upgrading State and Local Capacity (ASPR and CDC)	350.0	350.0	47.5
Vaccination Campaign (CDC)	1,949.2	1,373.0	379.8
Domestic Response (CDC)	242.3	61.6	18.6
International Response (CDC)	48.2	27.1	3.7
Communications (CDC)	33.2	9.1	1.9
Compensation (HRSA)	2.0	0.1	0.0
Ongoing Activities with H1N1 Impacts (ASPR)	179.0	73.7	25.1
Total Available Funding	6,149.7	3,770.2	1,907.5